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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,336	07/25/2005	Daniel Cohen	G-194US04PCT	9315
23557 7590 11/08/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 11/08/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/519,336	Applicant(s) COHEN ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43,45,63,65,66,68,69,71,72 and 74-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43,45,63,65,66,68,69,71,72 and 74-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/24/7</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 43, 45, 63, 65, 66, 68, 69, 71, 72 and 74-80 have been amended and claims 44, 46-54, 62, 64, 67, 70 and 73 have been cancelled as requested in the amendment filed on September 24, 2007. Following the amendment, claims 43, 45, 63, 65, 66, 68, 69, 71, 72 and 74-82 are pending in the instant application.

Claims 43, 45, 63, 65, 66, 68, 69, 71, 72 and 74-82 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on September 24, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 43, 45, 63, 65, 66, 68, 69, 71, 72 and 74-82 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 11 of Paper mailed on April 23, 2007.

Briefly, the instant claims are directed to methods of screening candidate modulator compounds of a protein phosphatase 2A (PP2A), wherein the compounds are asserted to be used as candidate drugs to treat mental disorders. However, there is no disclosure of the specific biological significance of PP2A phosphatase with respect to a particular mental disease or disorder; therefore, the Examiner maintains that the evidence of record is inadequate to support a specific, substantial and credible utility of the claimed method.

Applicant traverses the rejection on the premise that the rejection is in conflict with the MPEP and the case law pertained to 35 U.S.C. 101 (p. 7 of the Response). Applicant further cites the decision in *Cross v. Iizuka* and *Nelson v. Bowler* stating that “[k]nowledge of the pharmacological activity of any compound is obviously beneficial to the public [and] adequate proof of any such activity constitutes a showing of practical utility” (bottom at page 8). Applicant’s review of the issue of utility, the case law that has been cited and the holding that is found in that case law is not disputed. The only point of disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

At p. 7-8 of the Response, Applicant submits that the instant specification and prior art disclose the following information, which supports the utility of the instant claimed invention:

(1) KCNQ2 forms a functional potassium channel, which is phosphorylated by kinases and binds to PP2A/B $\gamma$ ;

(2) phosphorylation or dephosphorylation of KCNQ channels is believed to be involved in the control of neuronal excitability (emphasis added);

(3) PP2A/B $\gamma$  is a brain and neuron specific polypeptide (Borsotto et al.);

(4) activity/phosphorylation state of KCNQ is modulated by lithium;

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(5) lithium is a compound known to treat bipolar disorder.

As an initial matter, the Examiner does not doubt or dispute any of the actual findings (data) presented in the instant specification. However, the disclosed results of experiments fail to establish support of the assertion that a compound, which modulates PP2A/B $\gamma$  or PP2A has “a pharmacological activity” with respect to any disease or disorder. As such, there appears to be no immediate patentable need for a method to screen for compounds that modulate PP2A activity.

The Court in *Brenner v. Manson* held that “[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” See *Brenner* 383 U.S. at 534, 148 USPQ at 695.

In the instant case, characterization of the interaction between KCNQ and PP2A, as the polypeptides being expressed in the brain and regulated by a drug known to treat bipolar disorder, is clearly not sufficient to establish the biological significance of this interaction to bipolar disorder or to any mental disorder in general. Since the instant specification fails to present any evidence or sound scientific reasoning that the KCNQ/PP2A activity/ binding has any specific physiologic effect in etiology or course of a mental disorder, a skilled practitioner would not reasonably believe that administration of a compound that modulates the activity or binding of KCNQ/PP2A would have any effect on the course of the disease. In the terms used by the *Brenner* Court, such a characterization does not provide a specific utility in currently available form.

Applicant presents a set of experimental findings and claims a method for screening for a compound asserted to be useful in treating mental disorder but the specification does not disclose how to interpret those data. Just as the process claimed in *Brenner* lacked utility because the specification did not disclose how to use the end-product, the method claims here lack utility, based on the use of the product, because the specification provides no meaningful guidance on how such information would allow those skilled in the art to use the compounds identified by the claimed method in a specific substantial way.

The Supreme Court in *Brenner* held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure that justifies granting him the right to exclude others. See *id.*

Thus, since the instant specification does not disclose a credible “real world” use for the method of screening for modulators of PP2A, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful. The instant rejection is maintained.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 43, 45, 63, 65, 66, 68, 69, 71, 72 and 74-82 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### *Conclusion*

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

November 6, 2007